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REGISTERED PATENT ATTORNEY

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December 9, 2004

Fred F. Behrens, M.D.
Doctors Office Center Suite 5200
Newark, New Jersey 07103-2499

Re: Intramedullary Nail-Based Bone Fracture Treatment
U.S. Serial No. 10/697,227

Dear Dr. Behrens:

Enclosed is a copy of a letter from the Examiner in charge of the above patent application in the United States Patent and Trademark Office, together with a copy of each reference cited in the letter.

The Examiner has identified two species of the invention, namely, the arrangement which includes a supplemental end support and arrangements which do not have the end support, and has required an election of one of the species for examination in the present application. In a telephone discussion with the Examiner, we elected the latter species, effectively eliminating only claims 11 and 17 from consideration at this time. However, please note that the allowance of a claim which is generic to both species would allow reinstatement of claims to the non-elected species.

The objection to the drawing and the rejection of claim 16 on formal grounds are easily obviated.

Please note that claims 12 through 15 have been allowed. These claims are directed to the method of using the apparatus disclosed in the application and are quite comprehensive. In addition, the Examiner has indicated that claims 16 and 17, also drawn to method, would be allowed if amended as indicated. As stated above, claim 17 is one of the claims directed to a non-elected species, but would be reinstated since the generic claim 12 has been found to be allowable. Thus, only claim 11 would remain withdrawn from consideration at this time.

The principal reference relied upon by the Examiner in rejecting all of the claims drawn to the apparatus is the patent to Palkovitz, cited by us in the Information Disclosure Statement filed with the application. The Examiner finds all of the elements of claim 1 disclosed in Palkovitz. Supplemental references to the

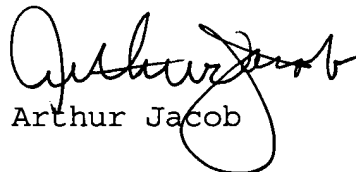
Marino and Perry patents are employed by the Examiner to show that features not disclosed in Palkovitz would be obvious additions.

We do not find the elements of claim 1 in Palkovitz. The reference lacks any suggestion that a drill guide can be coupled with pins secured to the long bone at locations spaced away from fractures adjacent either end of the long bone so as to provide a guide for drilling holes at the fractures, which holes then receive fixation screws. That arrangement achieves the objective of accurately locating fixation screws for fractures located adjacent the ends of the long bone without requiring incisions at the ends of the long bone for locating fixtures adjacent those ends. The supplemental references do not suggest any combination with Palkovitz which could render obvious some of the features of the more specific claims.

It appears that the Examiner has read the terms of the claims as broadly as possible in an effort to make the references fit the language of the claims; however, we believe that merely finding some structure which could be used to meet the terms of the claims does not render the claims anticipated by that structure. Thus, it may become necessary to amplify the language of the claims so as to better distinguish the claimed structural combination over the disclosures of the references, and to do so without narrowing the scope of the claims. We suggest that emphasis be placed upon the location and securement of the anchoring pins intermediate the ends of the long bone, where the bone is accessible with minimally invasive incisions, and the coupling of the drill guide with the anchoring pins for proper placement of the stabilizing fasteners. The references do not appear to suggest that combination for the particular use set forth in the already allowed method claims.

Please review the enclosed materials, together with the above comments, and then communicate with us so that we may decide upon an appropriate response to the enclosed letter. Any such response should be filed as early as possible, and before **March 1, 2005**, bearing in mind that the application has been granted special status and should be moved along as quickly as possible.

Sincerely yours,



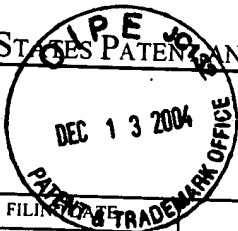
Arthur Jacob

A-02.37
Encls.

ARTHUR JACOB
COUNSELLOR AT LAW



UNITED STATES PATENT AND TRADEMARK OFFICE



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,227	10/30/2003	Alfred F. Behrens	A-02.37	1958

7590
12/01/2004
Arthur Jacob
25 East Salem Street
P.O. Box 686
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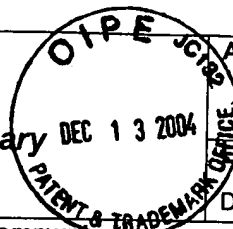
EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

DEC 13 2004



Application No.

00/697,227

Examiner

David Comstock

Applicant(s)

BEHRENS, ALFRED F.

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 17 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-15 is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 30 October 2003.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 112704.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

- I. Figs. 2, 3 and 4 (claims 1-10 and 12-16)
- II. Figs. 5 and 14 (claims 1, 2, 5-12 and 14-17)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 5-10, 12, and 14-16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Arthur Jacob on 18 November 2004 a provisional election was made without traverse to prosecute the invention of species I, claims 1-10 and 12-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11 and 17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the reference to "the method of claim 11" renders the claim unclear since claim 11 does not recite a method, but rather an apparatus. For examination purposes, and as best understood, claim 16 has been considered as depending from method claim 12. It is noted that claim 17, although withdrawn from consideration, if rejoined, would likewise improperly depend from apparatus claim 11. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Palkovitz (2,812,761; cited by applicant).

Palkovitz discloses a fixation device comprising an intramedullary nail 3 having an elongate shank and a plurality of transverse sockets and passages 3a (i.e. bores) spaced from ends of the nail (see Figs. 1 and 4). Anchoring pins 7 extend through the sockets. Member 5 has passages 5a, extending normal to the longitudinal axis of the

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shank, which are capable of functioning as drill guides (see Fig. 1). The member 5 is coupled to the anchoring pins, at least with respect to every degree of freedom except for translation in an axial direction of the anchoring pins.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palkovitz (2,812,761; cited by applicant) in view of Marino (4,733,654).

Palkovitz discloses the claimed invention except for the the complementary screw threads between the anchoring pins and the nail. Marino teaches a fixation device having complementary threads between pins 26, 27 and a nail 1 to allow the anchoring pins to engage the bores 24, 25, in order to stabilize the femoral nail and facilitate the healing process (see Fig. 1; col. 1, lines 5-9; and col. 3, lines 3-5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the fixation device of Palkovitz with complementary threads between the anchoring pins and the sockets of the nail, in view of Marino, in order to engage and stabilize the femoral nail and facilitate the healing process.

Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palkovitz (2,812,761; cited by applicant) in view of Perry (5,766,174; cited by applicant).

Palkovitz discloses the claimed invention except for explicitly disclosing that the passages may be provided at an obtuse angle with respect to the nail. Perry teaches that passages, e.g. 33, of a fixation device 20 may be oriented at an angle (including obtuse), in order to accommodate varying fractures and to better affix the bone fragments (see e.g. Fig. 6 and col. 4, lines 13-22). It would have been obvious to provide the fixation device of Palkovitz with passages at an obtuse angle with respect to the nail, in view of Perry, in order to accommodate varying fractures and to better affix the bone fragments. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges--for example, as here, the range of optimum or workable passage angles--involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

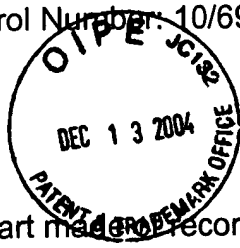
Allowable Subject Matter

Claims 12-15 are allowable over the prior art of record.

Claim 16 would be allowable if rewritten to depend from claim 12, as described above.

Claim 17 is subject to rejoinder and allowance if it is amended to depend from claim 12.

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Conclusion

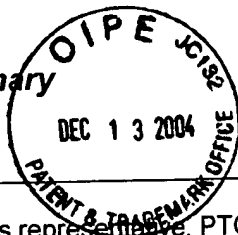
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.

D. Comstock
27 November 2004

EDUARDO C. ROBERT
PRIMARY EXAMINER

Interview Summary



Application No.

10/697,227

Applicant(s)

BEHRENS, ALFRED F.

Examiner

David Comstock

Art Unit

3732

All participants (applicant, applicant's representative, PTO personnel):

(1) David Comstock.

(3) _____.

(2) Arthur Jacob.

(4) _____.

Date of Interview: 18 November 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: 1-17.


Identification of prior art discussed: N/A.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.


Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's representative elected without traverse species I, claims 1-10 and 12-16 (corresponding to Figs. 2, 3 and 4). Accordingly, claims 11 and 17 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

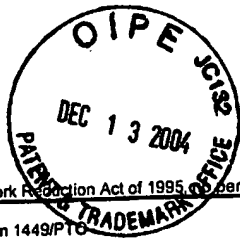
(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.


EDUARDO C. ROBERT
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	
Filing Date	October 30, 2003
First Named Inventor	Alfred F. Behrens
Art Unit	
Examiner Name	
Attorney Docket Number	A-02.37

Sheet 1 of 1

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
CE		US- 2,812,761	11-12-1957	Palkovitz	
		US- 4,281,649	08-04-1981	Derweduwen	
		US- 4,667,664	05-26-1987	Taylor et al	
		US- 4,865,025	09-12-1989	Buzzi et al	
		US- 5,176,681	01-05-1993	Lawes et al	
		US- 5,207,682	05-04-1993	Cripe	
		US- 5,766,174	06-16-1998	Perry	
		US- 5,766,179	06-16-1998	Faccioli et al	
		US- 6,033,407	03-07-2000	Behrens	
		US- 6,221,074	04-21-2001	Cole et al	
		US- 6,322,591	11-27-2001	Ahrens	
		US- 2001/0034523	10-25-2001	Nelson	
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁴
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

Examiner
SignatureDate
Considered

11/18/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Notice of References Cited	Application/Control No. 10/697,227	Applicant(s)/Patent Under Reexamination BEHRENS, ALFRED F.	
	Examiner David Comstock	Art Unit 3732	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-4,733,654	03-1988	Marino, James F.	606/64
	B	US-2003/0073999	04-2003	Putnam, Matthew D.	606/62
✓	C	US-3,996,931	12-1976	Callender, Jr., George R.	606/65
✓	D	US-6,702,815	03-2004	Kuntz, Charles	606/60
✓	E	US-2003/0069581	04-2003	Stinson et al.	606/62
✓	F	US-2003/0114855	06-2003	Wahl et al.	606/67
✓	G	US-5,785,709	07-1998	Kummer et al.	606/56
✓	H	US-5,474,561	12-1995	Yao, Meei-Huei	606/98
✓	I	US-4,913,137	04-1990	Azer et al.	606/64
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.